

10/566012

IAP20 Resubmittal 25 JAN 2006

"Express Mail" mailing label number EV 393133036 US

Date of Deposit

24 Jun. 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

QUEEN Thomas

Printed Name

Queen Thomas

Signature

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Louis Nickolaus Jungheim, et al. )  
)  
For : Compounds, Methods and Formulations for )  
the Oral Delivery of a Glucagon-Like Peptide )  
(GLP)-1 Compound or A Melanocortin-4 )  
Receptor (MC4) Agonist Peptide )  
)  
Docket No. : X-16903 )

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provide a copy of each of the listed documents for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

IAP20 RECEIVED 25 JAN 2006

Applicants request consideration of this information.

Respectfully submitted,

*Paula K. Davis*

Paula K. Davis  
Attorney for Applicants  
Registration No. 47,517  
Phone: 317-433-3422

Eli Lilly and Company  
Patent Division, PKD  
P.O. Box 6288  
Indianapolis, Indiana 46206-6288

18 January 2006

IAP20 Rec'd PCT/PTO 25 JAN 2006

FORM PTO 1449 (modified)  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X-16903	Serial No. <b>10/566012</b>
	First Applicant Louis Nickolaus Jungheim, et al.	
	Filing Date	Group

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Pages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
↓ N.C./	AA	US 3,578,671	05-11-1971	Wyeth & Bros. Ltd.	
	AB	US 4,239,754	12-16-1980	Sache, et al.	
	AC	US 4,925,673	05-15-1990	Steiner, et al.	
	AD	US 5,965,121	10-12-1999	Ho Koc-Kan et al.	
	AE	US 5,541,155	07-30-1996	Leone-Bay, et al.	
	AF	US 5,693,338	12-02-1997	Milstein, S.	
	AG	US 5,976,569	11-02-1999	Milstein, S.	
	AH	US 5,643,957	07-01-1997	Leone-Bay, et al.	
	AI	US 5,650,386	07-22-1997	Leone-Bay, et al.	
	AJ	US 5,820,881	10-13-1998	Milstein, S.	
	AK	US 5,866,536	02-02-1999	Leone-Bay, et al.	
	AL	US 5,955,503	09-21-1999	Leone-Bay, et al.	
	AM	US 5,965,121	10-12-1999	Leone-Bay, et al.	
	AN	US 5,989,539	11-23-1999	Leone-Bay, et al.	

Examiner Signature	/Nizal Chandrakumar/	Date Considered	04/12/2008
-----------------------	----------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hours Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

FORM PTO 1449 (modified)  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X-16903	Serial No. <b>10/566012</b>
	First Applicant Louis Nickolaus Jungheim, et al.	
	Filing Date	Group

/N.C./	AO	US 6,001,347	12-14-1999	Leone-Bay, et al.	
/N.C./	AP	US 6,071,510	06-06-2000	Leone-Bay, et al.	
/N.C./	AQ	US 6,100,298	08-08-2000	Leone-Bay, et al.	
/N.C./	AR	US 6,242,495	06-05-2001	Leone-Bay, et al.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
/N.C./	BA	WO 00/40203	07-13-2000			
	BB	WO 00/47188	08-17-2000			
	BC	WO 00/50386	08-31-2000			
	BD	WO 00/59863	10-12-2000			
	BE	WO 01/32130	05-10-2001			
	BF	WO 01/44199	06-21-2001			
	BG	WO 01/51454	07-19-2001			
	BH	WO 02/02509	01-10-2002			
	BI	WO 03/072195	09-04-2003			
/N.C./	BJ	WO 05/000339	01-06-2005			

Examiner Signature	/Nizal Chandrakumar/	Date Considered	04/12/2008
--------------------	----------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hours Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

IAP20 Rec'd PCT/PTO 25 JAN 2006

FORM PTO 1449 (modified)  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X-16903	Serial No. <b>107566012</b>
	First Applicant Louis Nickolaus Jungheim, et al.	
	Filing Date	Group

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
/N.C./	CA	DAI, Y. et al. "A Novel Series of Histone Deacetylase Inhibitors Incorporating Hetero Aromatic Ring Systems as Connection Units." Science Direct, Bioorganic and Medicinal Chemistry Letters 13, pp. 3817-3820, 2003.	
/N.C./	CB	PATEL, H. et al. "Oral Administration of Insulin By Encapsulation Within Liposomes." FEBS LETTERS, Vol. 62, No. 1, pp. 60-63, 1976.	
/N.C./	CC	HASHIMOTO, A. et al. "Effects of Oral Administration of Positively Charged Insulin Liposomes on Alloxan Diabetic Rats: Preliminary Study." Endocrinology Japan, Vol. 26, No. 3, pp. 337-344, 1979.	

Examiner Signature	/Nizal Chandrakumar/	Date Considered	04/12/2008
-----------------------	----------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. Burden Hours Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.